4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1182]

Unique Device Identification System: Small Entity Compliance Guide; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Unique Device Identification System: Small Entity Compliance Guide" for a final rule published in the Federal Register of September 2013. This small entity compliance guide (SECG) intends to provide, in plain language, the requirements of the regulation and to help small businesses understand and comply with the regulation.

DATES: Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit written requests for single copies of the SECG entitled "Unique Device Identification System: Small Entity Compliance Guide" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: For CDRH questions regarding this document, contact UDI Regulatory Policy Support, 301-796-5995, email: udi@fda.hhs.gov. For CBER questions regarding this document, contact Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled: "Unique Device Identification System: Small Entity Compliance Guide."

Section 226 of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) and section 614 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144) amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification system for medical devices.

In the Federal Register of September 24, 2013 (78 FR 58785), FDA published a final rule establishing a unique device identification system (the UDI Rule). Some parts of the rule became effective on October 24, 2013; the remaining parts became effective on December 23, 2013. In addition, certain provisions within the rule have later compliance dates. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public

Law 104-121), FDA is making available this SECG stating in plain language the legal requirements of the September 24, 2013, final rule.

This level 2 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801 and 830 have been approved under OMB control number 0910-0720; the collections of information in part 803 have been approved under OMB control number 0910-0437; the collections of information in part 806 have been approved under OMB control number 0910-0359; the collections of information in part 810 have been approved under OMB control number 0910-0432; the collections of information in part 814 have been approved under 0910-0231; the collections of information in part 821 have been approved under OMB control number 0910-0442; and the collections of information in part 822 have been approved under OMB control number 0910-0449.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at http://www.regulations.gov, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Persons unable to download an electronic copy of "Unique Device Identification System: Small Entity Compliance Guide" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400046 to identify the guidance you are requesting.

Dated: September 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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